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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,935

05/04/2005

Rubina Mian

117-541

9653

23117

7590

03/12/2007

NIXON & VANDERHYE, PC

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ARLINGTON, VA 22203

EXAMINER

WOOD, AMANDA P

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/533,935	MIAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amanda P. Wood	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5-14, 16, 17, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-14, 16, 17, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicant's response and amendment filed 8 December 2006 have been received and entered.

Claims 1-2, 5-14, 16-17, and 23-24 have been examined on the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5-14, 16-17, and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Based upon the amendments to claim 1 regarding part (c), further clarification is necessary to determine the meaning of the claims. In particular, part (c) of claim 1 is still unclear as to how the comparing step is being performed (i.e., superoxide production above basal observed in the test whole blood sample is being compared to superoxide production above basal observed in the control whole blood sample, but it is unclear when a measurement was made for the basal test whole blood sample, to provide a second basal measurement, one for the test sample, and one for the control sample).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-11, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukamoto et al (Nippon Eisigaku Zasshi 1994) in view of Pfefferkorn (US 5,492,816).

Tsukamoto et al does not expressly teach a method wherein superoxide production is detected using luminol as an amplifier and the resulting chemiluminescence is measured.

Tsukamoto et al beneficially teach a method wherein whole blood samples from mice (i.e., mammals) were tested for superoxide production from neutrophils compared to that of neutrophils from control samples (i.e., samples obtained from mice which were free from stress-induced activation, and free from the psychological stressor that the test subjects were exposed to). The mice in the study taught by Tsukamoto et al were divided into three groups, studying the effects of crowding on immune functions in mice

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(i.e., studying the effect of a psychological stressor on a physiological status in a mammal). Tsukamoto et al placed control mice into groups of four mice per cage, crowd I mice into four mice per small space, and crowd II mice into sixteen mice per cage. Tsukamoto et al teach that the superoxide production of blood neutrophils in crowd II mice tended to be depressed as compared to control mice. Tsukamoto et al beneficially teach that these results suggest that the complexity of interrelationships among mice caused by an increase in the number of animals per cage is a very important stress factor (see, for example, Abstract).

Pfefferkorn beneficially teaches a method wherein luminol is used to measure the chemiluminescence in superoxide anion assays triggered by PMA or FMLP in cells such as polymorphonuclear nucleocytes (i.e., neutrophils). In particular, Pfefferkorn beneficially teaches that inducers, in conjunction with luminol chemiluminescence assays for superoxide, are useful for enhancing detection of superoxide (see, Abstract, and col. 4, lines 15-35, and col. 3, lines 50-65).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Tsukamoto et al based upon the beneficial teachings provided by Pfefferkorn with respect to the art-recognized method of enhancing detection of superoxide anion using an inducer, such as FLMP or PMA, and an amplifier, such as luminol, as discussed above. Furthermore, the Tsukamoto et al particularly point out that psychological stressors such as crowding among mice cause a depression in superoxide production by blood neutrophils as compared to mice not under such psychological stress, and therefore, it would have

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been obvious and beneficial for the skilled artisan to use the methods taught by Tsukamoto et al in conjunction with the methods of Pfefferkorn so as to determine whether an individual is experiencing a changed physiological status arising from exposure to a psychological stressor. The result-effective adjustment of particular conventional working conditions (e.g., using a particular inducer or particular type of sample, performing the test on a particular type of individual) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Claims 1-2, 12-14, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukamoto et al (Nippon Eisigaku Zasshi 1994) in view of Carlson et al (US 6,319,953).

Tsukamoto et al beneficially teach a method wherein whole blood samples from mice (i.e., mammals) were tested for superoxide production from neutrophils compared to that of neutrophils from control samples (i.e., samples obtained from mice which were free from stress-induced activation, and free from the psychological stressor that the

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test subjects were exposed to). The mice in the study taught by Tsukamoto et al were divided into three groups, studying the effects of crowding on immune functions in mice (i.e., studying the effect of a psychological stressor on a physiological status in a mammal). Tsukamoto et al placed control mice into groups of four mice per cage, crowd I mice into four mice per small space, and crowd II mice into sixteen mice per cage. Tsukamoto et al teach that the superoxide production of blood neutrophils in crowd II mice tended to be depressed as compared to control mice. Tsukamoto et al beneficially teach that these results suggest that the complexity of interrelationships among mice caused by an increase in the number of animals per cage is a very important stress factor (see, for example, Abstract).

Carlson et al beneficially teach a method of screening for a stress-relieving drug, wherein a test compound is administered to an individual and the individual is then exposed to a psychological stressor. Furthermore, Carlson et al beneficially teach that measurements are made to determine the effect of the stress on the individual, and then compared to the individual's own baseline or to other individuals of the same species which receive no test compound. Furthermore, Carlson et al particularly teach a method for treatment of stress (i.e., anxiety) which comprises administration to a patient in need (i.e., a patient suffering from stress) an amount of a compound that gives effective relief of said stress, as determined by the methods taught by Carlson et al (see, for example, Abstract, col. 36, lines 10-65, and col. 42, lines 15-67).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Tsukamoto et al based

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upon the beneficial teachings provided by Carlson et al with respect to the art-recognized method of screening for stress-relieving drugs and treating individuals suffering from stress by providing a stress-relieving treatment, as discussed above. Furthermore, the Tsukamoto et al particularly point out that psychological stressors such as crowding among mice cause a depression in superoxide production by blood neutrophils as compared to mice not under such psychological stress, and therefore, it would have been obvious and beneficial for the skilled artisan to use the methods taught by Tsukamoto et al in conjunction with the methods of Carlson, so as to determine whether an individual is suffering from stress, screen for a drug to treat said said, and treat said individual with a treatment to relieve the stress. The result-effective adjustment of particular conventional working conditions (e.g., using a particular inducer or particular type of sample, performing the test on a particular type of individual, or using a particular means of screening for a drug) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.



***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER